JAN 12 2001

510(k) Summary

K003967

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 576-3544

Contact Person: Kay A. Taylor

Date Prepared: December 20, 2000

2) Device name

Proprietary name:	Elecsys CA 125 II CalCheck
Common name:	Calibration Verification Material
Classification name:	Single (specified) analyte controls (assayed + unassayed)

3) Predicate device

We claim substantial equivalence to the currently marketed Elecsys CA 125 II CalCheck (K981278).

510(k) Summary, Continued

4) Device Description

The Elecsys CA 125 II CalCheck is manufactured using horse serum in level 1 and human serum in level 2 & 3, preservatives and CA 125. The analyte is appropriately spiked into the CalCheck matrix to the correct CalCheck concentration levels. The Elecsys CA 125 II CalCheck is provided in a lyophilized format and is traceable to the Enzymun CA 125 II.

5) Intended use

For use in the verification of the calibration established by the Elecsys CA 125 II reagent on the Elecsys 2010 and 1010 Immunoassay analyzers.

6.) Substantial equivalence

The table below indicates the similarities between the modified Elecsys CA 125 II CalCheck and the predicate, Elecsys CA 125 II CalCheck (K981278). In summary, the Elecsys CA 125 II CalCheck described in this submission is, in our opinion, substantially equivalent to the predicate device.

Comparison of Proposed and Predicate Device

Topic	Modified Elecsys CA 125 II CalCheck	Elecsys CA 125 II CalCheck (cleared K981278)
Intended Use	Same	For use in the verification of the calibration established by the Elecsys CA 125 II reagent on the Elecsys 2010 and 1010 Immunoassay analyzers.
Indication for Use	The Elecsys CA 125 II CalCheck is intended for use in periodic verification of the calibration of the Elecsys CA 125 II reagent calibration.	Elecsys CalCheck CA 125 II calibration verification solutions comprise three levels – low, mid, and high – each with a defined CA 125 II concentration. The low solution concentration is near the lower detection limit of the assay. The mid solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range. The Elecsys CalCheck CA 125 II is intended for use in periodic verification of the calibration of the Elecsys CA 125 II assay.
Format	Lyophilized	Liquid
Traceabilility	Same	vs. Enzymun CA 125 II
Matrix	Level 1 – horse serum Levels 2 & 3- human serum	Human plasma

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 2 2001

Ms. Kay A. Taylor
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K003967
Trade Name: Elecsys CA 125 II CalCheck
Regulatory Class: I
Product Code: JJX
Dated: December 20, 2000
Received: December 22, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarke notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003967
Device Name: **Elecsys CA 125 II CalCheck**

Indications for Use:

The Elecsys CA 125 II CalCheck is intended for use in periodic verification of the calibration of the Elecsys CA 125 II reagent calibration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003967

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)